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8.0 Premarket Notification 510(k) Summary

[As required by section 807.92(c)]

Applicant:	Michael J. Morris R2 Diagnostics, Inc. 412 South Lafayette Blvd. South Bend, IN 46601 USA
Contact:	Dr. Peggy S. Carter R2 Diagnostics, Inc. 412 South Lafayette Blvd. South Bend, IN 46601 TEL: (574) 288-4377 FAX: (574) 288-2272
Date:	October 22, 2003
Trade Name:	R2 Diagnostics Phospholin ES
Common Name:	Activated Partial Thromboplastin Time
Classification Name:	Test, Time, Partial Thromboplastin (per 21 CFR section 864.7925)
Comparison Device:	Dade Actin FSL, K863594 Stago Calcium Chloride

Description of the Device and Intended Use

R2 Diagnostics Phospholin ES is a liquid reagent containing ellagic acid as the activator and phospholipids derived from soybean lecithin. The reagent also contains buffer and preservatives. Phospholin ES is an *in vitro* diagnostic reagent intended for use for the performance of the activated partial thromboplastin time two-stage test (APTT) and related coagulation factor assays. Phospholin ES is sensitive to lupus anticoagulants. Phospholin ES as with any APTT test requires the addition on 0.02-0.025M Calcium Chloride to perform the assay.

Summary of Substantial Equivalence Comparisons

R2 Diagnostics Phospholin ES and Calcium Chloride are substantially equivalent in intended use and performance to Dade Actin FSL and Stago Calcium Chloride. Both the predicate device and the proposed product are formulated to detect deficiencies in factors II, V, VIII, IX, XI, and XII (APTT and APTT-based factor assays). Both reagents are also sensitive to lupus anticoagulants. In correlation studies, APTT testing of normal and abnormal patients, as well as samples from patients positive for lupus anticoagulants were tested using both reagents. APTT testing at two sites and on two different instrument types yielded correlation coefficients of R = 0.92 (photo-optical), slope = 0.864 and R = 0.93 (mechanical), slope = 1.09. In addition correlation coefficients of R = 0.94 (photo-optical), slope = 0.866 and R = 0.99 (mechanical), slope = 0.627 were obtained for lupus anticoagulant positive samples. Within-run and between-run precision studies were also performed and CV's of less than 3% were obtained for the proposed device. CV's of less than 3% are also reported for the predicate device in the manufacturers directional insert. The Calcium Chloride products are identical in formulation of 0.025M Calcium Chloride.

Conclusion: Substantial Equivalence Statement

In Summary, the identical intended use, similar technological characteristics and the performance data provided in this premarket notification demonstrate that R2 Phospholin ES and Calcium Chloride are substantially equivalent to Dade Actin FSL and Stago Calcium Chloride.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Peggy Carter, Ph.D.
Director, Product Development
R2 Diagnostics, Inc.
412 S. Lafayette Boulevard
South Bend, Indiana 46601

Re: k033471
Trade/Device Name: Phospholin ES and Calcium Chloride
Regulation Number: 21 CFR § 864.7925
Regulation Name: Partial Thromboplastin Time Tests
Regulatory Class: II
Product Code: GGW
Dated: January 8, 2004
Received: January 14, 2004

Dear Dr. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033471

Device Name: Phospholin ES and Calcium Chloride

Indications for Use:

The Phospholin ES Activated Partial Thromboplastin Time reagent is a liquid activated reagent with phospholipids derived from soybean lecithin for use in the determination of Activated Partial Thromboplastin Time (APTT) and related coagulation procedures. Phospholin ES is to be used as an APTT reagent (qualitative assay) on patient plasma for the routine screening in the general patient population for deficiencies involving the intrinsic pathway of coagulation. Phospholin ES is sensitive to lupus-like inhibitors.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033471

(Posted November 13, 2003)